

Message Text

UNCLASSIFIED

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ORIGIN HEW-06

INFO OCT-01 AF-08 ARA-10 EUR-12 EA-09 ISO-00 OES-06 COME-00
MED-03 /055 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: BROYSTER

EUR/EX:JLTULL(INFO)

EA/EX:JRCUNNINGHAM(INFO)

ARA/EX:CJACOBINI(INFO)

AF/EX:JTIERNEY(INFO)

-----080619Z 090850 /14

R 072223Z FEB 77

FM SECSTATE WASHDC

TO AMEMBASSY MADRID

AMEMBASSY LAGOS

AMEMBASSY ATHENS

AMCONSUL HONG KONG

AMEMBASSY ROME

AMEMBASSY KUALA LUMPUR

AMEMBASSY BUENOS AIRES

AMEMBASSY CANBERRA

AMEMBASSY PARIS

AMEMBASSY MEXICO

AMEMBASSY THE HAGUE

AMEMBASSY PRETORIA

AMEMBASSY WELLINGTON

UNCLAS STATE 027361

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, SP, NI, GR, HK, IT, MY, AR,

SUBJECT: SUBPOTENT IN VITRO DIAGNOSTIC PRODUCT (RECALL
T-002-7)

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1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: VERSATOR PEDIATRIC IN VITRO DIAGNOSTIC,
3ML. VIAL, 10 VIALS PER CARTON. THE PRODUCT IS USED AS A
BILIRUBIN REFERENCE AND CONTROL FOR IN VITRO TESTING OF
CHILDREN'S SERUM.

LOT NUMBERS INVOLVED: 2361125 AND 4B055

MANUFACTURER/RECALLING FIRM:

GENERAL DIAGNOSTICS, DIVISION OF WARNER LAMBERT,
201 TABOR ROAD
MORRIS PLAINS, NEW JERSEY 07950

2. REASON FOR RECALL:

CUSTOMER COMPLAINTS REPORTED A FAILURE TO RECOVER LABEL
VALUES FOR BILIRUBIN. THE FIRM'S QUALITY CONTROL TESTING

FAILED TO CONFIRM CUSTOMER PROBLEMS, HOWEVER, THEY DID
RECOVER VALUES SLIGHTLY BELOW THE LABEL STATEMENT.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY HAVE RECEIVED RECALL LETTERS DATED 13
OCTOBER 1976 FOR LOT 2361125 AND 19 NOVEMBER 1976 FOR
LOT 4B055. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING
THIS RECALL SHOULD BE DIRECTED TO FIRM. CONTACT AT FIRM
IS R. A. WEBB, MANAGER QUALITY ASSURANCE AND REGULATORY
COMPLIANCE, TELEPHONE 800-631-3060.

4. FOREIGN CONSIGNEES AS FOLLOWS:

LABORATORIO SUBSTANCIA, S.A.
POLIGONO INDUSTRIAL MANSO
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MATEU S/N
PRAT DE LLOBREGAT
BARCELONA, SPAIN
(SOLD TO)

LABORATORIOS SUBSTANCIA, S.A.
C/O COMMERCIAL COMBALIA-SAGRERA S.A.
BARCELONA AIRPORT
(CONSIGNED TO)

PARKE DAVIS AND CO
P O BOX 2784
LAGOS, NIGERIA
(SOLD TO)

P. BACACOS
OMONIA SQUARE
ATHENS, GREECE
(SOLD TO)

P. BACACOS
C/O GENERAL BANK OF GREECE
SOCRATOUS BRANCH
ATHENS, GREECE
(CONSIGNED TO)

W-L HONG KONG LTD N.V. SUBSTANTIA
NEW INDUSTRIAL BUILDING "D" INDUST. 9-19
7TH FLOOR, TONG CHONG STREET MIJDRECHT, NETHERLANDS
(TAIKOO SUGAR REFINERY) (SOLD TO)
QUARRY BAY, HONG KONG
(SOLD TO) WARNER-LAMBERT

37 BANKS ROAD
A. ANGIOLINI AND CO SPA MT. WELLINGTON
CASELLA POSTALE 4077 AUCKLAND, NEW ZEALAND
MILAN, ITALY (SOLD TO)
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(SOLD TO)

WARNER-LAMBERT (MFG) SDN
BERHAD
JALAN 13/4A
PETALING JAYA, SELANGOR
MALAYSIA
(SOLD TO)

W. R. WARNER Y CIA, S.A.
SARMIENTO 3401
BUENOS AIRES, ARGENTINA
(SOLD TO)

WARNER-LAMBERT PRY, LTD
32-40 CAWARRA ROAD NORTH
CARINGBAH, N.S.W. 2229
AUSTRALIA
(SOLD TO)

PRECIBIO S.A.
58 RUE DE DESSOUS DES BERGES
PARIS 13E FRANCE
(SOLD TO)

CIA MEDICINAL "LA CAMPANA"
S.A. DE C.V.
AVENIDA DIVISION DEL NORTE 3443
ZONA POSTAL 21
MEXICO, D.F., MEXICO

TRAFICO ABRCO INTER.
AEROPUERTO INTER
DE LA CIUDAD DE MEXICO D.F.
(CONSIGNED TO)
VANCE
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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 07-Feb-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE027361
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770044-0250
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770265/aaaacfv1.tel
Line Count: 181
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 0c744cca-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 18-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3388075
Secure: OPEN
Status: NATIVE
Subject: SUBPOTENT IN VITRO DIAGNOSTIC PRODUCT (RECALL T-002-7) UNCLASSIFIED
TAGS: OGEN, ETRD, TBIO, SP, NI, GR, HK, IT, MY, AR, US
To: MADRID LAGOS MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/0c744cca-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009